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The 30th Anniversary of the Hatch-Watchman Act: Foreword

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FOREWORD

Orrin G. Hatch[†]

It's hard to believe that it's been thirty years since Congressman Henry Waxman and I joined together to pass the Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Act. The articles that follow in this issue of the *William Mitchell Law Review* are a testament to the continued success of this legislation in spurring the development and marketing of generic drugs while providing unprecedented new intellectual property incentives designed to encourage continued investment in new medicines by brand name drug companies. More importantly, the ongoing debate reminds us that to maintain this momentum, we need to continuously look for the most effective and efficient means of incentivizing development of lifesaving drugs while ensuring that those drugs are widely available to the American people.

I like to think that I've kept up with how Hatch-Waxman is faring after thirty years, but I'll be the first to admit that there are many commentators, some of whose work appears in this very issue, who can provide a far more detailed analysis of the current issues than I will provide here. What I hope you will find more interesting, and perhaps even insightful, is the story of how the Hatch-Waxman Act came to be—the triumphs and tribulations of the legislative process that don't make it into the legislative history.¹

The state of the pharmaceutical industry in the 1980s is well documented. Major research companies were increasingly frustrated with spending hundreds of millions of dollars to develop a new product, only to see its patent life undercut by delays in the

[†] Member, United States Senate (R-Utah). Senator Hatch chaired the Senate Committee on Labor and Human Resources from 1981–1987. He is a former Chairman of the Senate Committee on the Judiciary, where he is currently the senior-most Republican. Senator Hatch is also ranking member of the Senate Committee on Finance.

1. For further background on the Hatch-Waxman Act, see ORRIN HATCH, *SQUARE PEG: CONFESSIONS OF A CITIZEN SENATOR* 70–81 (2002).

approval of new drugs by the Food and Drug Administration (FDA). Meanwhile, the domestic generic pharmaceutical industry was realizing only a fraction of its potential. The handful of existing companies were struggling because they could not afford to replicate the same expensive and time-consuming safety and efficacy trials undertaken by the pioneer firms, as the FDA required them to do, and still sell the drug at a reduced price.²

In sum, the FDA's regulatory system was discouraging brand innovator companies from investing in new research and development. At the same time, it was blocking the introduction of low-cost generic products. No one was benefiting—not the brand companies, not the generic firms, and not consumers. Yet neither the brands nor the generics could push legislation through Congress to address their respective problems; each side had enough clout to stop the other's legislative initiatives. Any legislative solution—and one was desperately needed—would have to address the concerns of both.

I recognized the need for reform shortly after becoming chairman of the U.S. Senate Committee on Labor and Human Resources in 1981. Despite the obvious need for reform at the FDA and relief not only for brand and generic manufacturers, but more importantly, for the American people, it was slow going. It took three years of countless meetings and hearings before I succeeded in convincing both Congress and the public that this was something that needed to be done. More importantly, by that point I was confident that my staff and I finally understood the positions of the various interested parties and what they really needed, as opposed to what they demanded in public. In the spring of 1984, however, political realities were threatening any hope of progress. The end of the session was quickly approaching, and because 1984 was a presidential election year, the Senate was already beginning to slide into the traditional partisan bickering and posturing that dominate the lead up to a major election. If there was to be any hope of passing a bill under these circumstances, I knew that I needed a strong bipartisan showing.

I found a willing ally in Representative Henry Waxman, the liberal Democrat from California and, at the time, the chairman of

2. See generally CONG. BUDGET OFFICE, HOW INCREASED COMPETITION FROM GENERIC DRUGS HAS AFFECTED PRICES AND RETURNS IN THE PHARMACEUTICAL INDUSTRY (1998).

the House Health Subcommittee. If I thought securing such a respected Democratic ally would pave the way for progress, I was miscalculating the degree of animosity between the brand companies and generics. I invited a handful of industry leaders to meet with me personally in my office over several weeks. Not surprisingly, both sides were extremely skeptical of the other's intentions. Each thought the other's position was not only illogical but also self-serving.

The brand companies, led by Jack Stafford, the CEO of American Home Products, wanted legislation completely restoring every day of patent life lost while their approvals were being processed by the FDA. They needed a greater period of market exclusivity to recover the high cost of their research. Bill Haddad, representing the generics, disagreed. He responded that a drug's patent life might be shorter than that for other products, but the prices that could be charged were so disproportionate to the cost of production that immense profits could be realized in short periods of time.

Bill went on to insist that the generics needed to be able to bring a generic version of a drug to market immediately upon the expiration of the patent, without having to go through the extremely costly, time-consuming, and unnecessarily repetitive exercise of re-proving that the drug was safe. The brand companies responded that the generic firms were not real pharmaceutical companies. They didn't have adequate personnel, laboratories, or experience. They could not be trusted to make effective products on their own, and they posed a real health risk to an unsuspecting public.

Our discussions turned to a draft bill, and they proceeded to argue about every word. I pushed and prodded, alternating between being supportive and critical. At times, I was more of a therapist than a legislator, as I struggled to keep the discussion impersonal and constructive. The accusations continued, day after day. Toward the end of every session, either Bill or Jack would explode in a rage, swear off the negotiations, and stomp out of the room.

One day, Bill and Jack got angry at the same time. Jumping to their feet, they rushed to the door, shouting and blaming each other for the bill's lack of progress. Amazingly, they reached the frame simultaneously. Not wanting the other to win on anything, they both tried to jump through and smacked their heads. There

was a loud thud, and both stumbled back into the room, groaning in pain. I had been dreaming about doing just that for days. I had to turn away so they wouldn't catch me smiling.

In fairness, I wasn't immune to the pressure, either. After about a week, Jack was in the middle of one of his prolonged objections, refusing to let Bill interrupt to make a point. Bill just started talking. Soon, both were yelling, each trying to drown out the other. I leapt to my feet and slapped the table as hard as I could. "If you guys don't stop it, I'm going to kill somebody," I yelled, the words garbled but clear enough. The room fell silent. Both were dumbstruck. Murder was probably the only threat that they had not yet made, and they were clearly not expecting it to come from me. They stared at me in shock. I'm sure at that point I looked crazy enough to make good on the threat.

I know. It wasn't exactly my proudest moment. It certainly wasn't my most insightful negotiating tactic, yet amazingly, it worked. The discussion began again, but now Bill and Jack were competing to see who could be more courteous and subdued. Over time, we narrowed the issues in contention, reaching agreement on a variety of secondary problems. Ultimately, the brand companies decided they had more to gain by passing legislation than by stopping it and agreed in principle to the concept of a rapid generic approval process at the FDA. In exchange, the brand companies received patent term extensions or restorations to provide a greater period of market exclusivity. Once that occurred, everything else fell into place, and we quickly reached an agreement.

Some might be surprised by the amount of industry involvement with legislation of this kind, but it was critical. Quite simply, only someone experienced with the industry could understand the nuances and consequences of legislative wording. Great care had to be taken because we were changing the rules for a process that was ongoing. While we were negotiating, innovator and generic drugs were working their way through the approval process. Without proper care, it would be easy to unintentionally eliminate an entire product line with language that would appear completely logical and legitimate on its face.

After weeks of private negotiations, when the deal was finally made public, a majority in Congress recognized the agreement for what it was: a balanced compromise that refocused federal regulatory drug policy on innovation and research while creating

for the first time the real possibility of a vibrant generic industry that could save consumers billions of dollars.

Yet it takes more than just a good bill to get a vote in the U.S. Senate. Congress was getting ready to adjourn before the coming election, with literally only days left in the session. At that point, for a bill to move through the Senate, it would have had to be approved unanimously. Despite last-minute opposition, the bill was called up, approved, and adopted, without a recorded vote, by unanimous consent. Just a few days later, President Ronald Reagan signed the bill into law.³

The far-reaching impact of the Hatch-Waxman Act continues to be felt today, three decades after that flurry of legislative activity came to a close. While most other costs in the health care system have gone through the roof, generic pharmaceuticals have saved consumers, health care providers, businesses, insurers, and the government an enormous amount of money. According to the most recent data available, the use of generic medicines resulted in \$217 billion in savings in the U.S. health care system in 2012, and \$1.2 trillion from 2003 to 2012.⁴ There's no reason to believe that this tremendous growth won't continue in the years to come.

These cost savings come from a variety of sources:

Prior to the implementation of the Hatch-Waxman Act, 35% of top-selling drugs had generic competitors after patent expiration; now almost all do. The Generic Pharmaceutical Association points out that of 12,751 drugs listed in the Orange Book [the FDA's publication of approved drugs], 10,072 have generic substitutes available to consumers. Concurrently, the time to market for these generic products has decreased substantially. According to the Congressional Budget Office, in 1984 the average time between the expiration of a patent on a brand name drug and the availability of a generic was three years. Today, upon FDA approval a generic may be introduced immediately after patents on the innovator drug expire as companies are permitted to undertake clinical testing during the time period associated patents are in force.⁵

3. See Drug Price Competition and Patent Term Restoration (Hatch-Waxman) Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585.

4. GENERIC PHARM. ASS'N, *GENERIC DRUG SAVINGS IN THE U.S.* 1 (5th ed. 2013); see also U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-12-371R, *DRUG PRICING: RESEARCH ON SAVINGS FROM GENERIC DRUG USE* 9-11 (2012).

5. WENDY H. SCHACHT & JOHN R. THOMAS, CONG. RESEARCH SERV., R41114,

While these achievements deserve recognition by all Americans, we cannot rest on the laurels of this legislative achievement from thirty years ago. The pharmaceutical industry today differs significantly from what it was in the early 1980s when Jack and Bill were bashing heads in my office. “The cost of developing a drug has doubled, as has the number of clinical trials necessary to file a new drug application. The number of participants required for these trials has tripled. As the rate of return on investments in a new drug declined 12%, manufacturers often spend [research and development] dollars on developing improved versions of . . . an existing product” rather than taking risks to explore uncharted territory.⁶

We struck a balance thirty years ago—a balance in which not only brand companies and generics, but the American people, came out ahead. Is that still the appropriate balance today? I believe that the foundation laid by the Hatch-Waxman Act thirty years ago will continue to be the mechanism by which the government incentivizes development of lifesaving drugs while ensuring that those drugs are accessible to the American people. Nevertheless, we have an obligation to periodically reevaluate how the balance can be adjusted to account for the sweeping changes in the broader health care sector.

The articles that follow demonstrate how the success of the Hatch-Waxman Act inspires ideas on how to improve the effects of the Act through additional legislation, how to safeguard the correct judicial interpretation of legislative intent behind the Act, how to ensure the correct application of the Act by the FDA, and how to imitate the Act’s profound positive effects to benefit American medical device consumers.

In this anniversary year, I want to applaud the scholarship on these issues. By looking not only at the tremendous benefits that have flowed from the Hatch-Waxman Act, but also how our pharmaceutical and broader health care industries can continue to adapt to changing times, we are building on the progress we’ve made over the last thirty years so we can make sure that Americans young and old continue to reap the benefits of this important law.

ORRIN G. HATCH

THE HATCH-WAXMAN ACT: OVER A QUARTER CENTURY LATER, at i (2012).

6. *Id.*